Operationalizing the Right to Health through the Pandemic Influenza Preparedness Framework

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Developing states lack access to pandemic influenza vaccines. The provision of 'essential' medicines is a core, non-derogable obligation of the right to health in the International Covenant on Economic, Social and Cultural Rights (ICESCR), which states must fulfill as a minimum criterion. The ICESCR does not provide an exhaustive list of which drugs constitute "essential medicines," although influenza vaccine was listed as an essential medicine during the most recent influenza pandemics. This paper presents three, interlocking arguments: First, it argues that ensuring access to a vaccine during an influenza pandemic is a right to health obligation for all states. Second, it argues that the access threshold a state must meet in order to discharge its right to health obligation in respect of access to pandemic influenza vaccine is different to the access threshold with oral solid drugs, and attempts to quantify the vaccine access threshold. Third, it examines the extent to which the World Health Organization (WHO) Pandemic Influenza Preparedness Framework can enable developing states to meet the vaccine access threshold during an influenza pandemic, and discharge their right to health obligations in this area, arguing that the Framework is unlikely to have a significant positive impact on access to vaccines by developing states during the next influenza pandemic.

INTRODUCTION

Vaccines are a key component in the response to an influenza pandemic; the timely administration of an influenza vaccine is the most effective public health intervention to halt the spread of infection and prevent mortality from influenza in adults,[1] the elderly,[2] and children.[3] However, developing states have long complained that they are unable to access influenza vaccines during a pandemic, despite their best efforts,[4] which may have implications for the ability of these states to meet their right to health obligations during an influenza pandemic.

In an attempt to remedy poor access to pandemic influenza vaccines in developing states the World Health Organization (WHO) enacted the Pandemic Influenza Preparedness (PIP) Framework in 2011. The Framework creates a virtual stockpile of "at least 150 million doses" of pandemic influenza vaccine, which developing states can procure from during a pandemic. The WHO has traditionally played a major role in the management of pandemic influenza outbreaks since its inception,[5] even going as far as to procure vaccines and distribute them to developing states that lack access during a pandemic, although this has been done on a largely ad-hoc basis.[6] The PIP Framework aims to improve the procurement of pandemic influenza vaccines by developing states[7] by creating a more structured approach to collection and distribution of donated pandemic influenza vaccines than the traditional ad-hoc manner in which the WHO has collected and donated vaccines. This is intended to ensure that the Pandemic influenza vaccines donated from manufacturers is not just given on an ad-hoc basis after orders from fee-paying states have been fulfilled, or once self-procuring states have determined they have excess pandemic influenza vaccines to meet their needs, as was the case with donations during 2009-H1N1.[8] Instead, donations of pandemic influenza vaccine may be included within the company obligations within Standard Material Transfer Agreements[9] completed via the PIP Framework, which mandate that a proportion of the real-time pandemic influenza vaccines production are reserved for, and transferred to, the PIP stockpile. This is a 'virtual' stockpile

of pandemic influenza vaccines which have been donated by vaccine manufacturers that the WHO will manage.[10]

The utility of the Framework at improving access to pandemic influenza vaccines during a pandemic has been explored in the literature, with no consensus being reached on how well, if at all, the PIP Framework can improve access in developing states. In order to advance these debates, this paper examines the utility of the Framework within the context of the right to health. It does this by examining how the PIP Framework improves the extent to which developing states can use the Framework to ensure that their populations have access to pandemic influenza vaccines. Prior to this analysis, it is necessary to demonstrate that ensuring access to pandemic influenza vaccines is an obligation binding upon states stemming from the right to health, and what a state ought to do in order to have discharged this obligation.

THE RIGHT TO HEALTH

The right to health has been referenced in international agreements since the 1940s.[11] The clearest articulation of the right to health has come in the International Covenant on Economic, Social and Cultural Rights (ICESCR), adopted by the United Nations (UN) General Assembly in 1966.[12] The ICESCR built upon the ideas put forward in the WHO Constitution and the Universal Declaration of Human Rights, and, in placing obligations upon states, outlined what sort of action a state could take in order to ensure that the highest attainable standard of health could be enjoyed by its citizens. Within the context of pandemic influenza vaccine access, clearly 2(c) is most directly relevant: action necessary for "[t]he prevention, treatment and control of epidemic, endemic, occupational and other diseases;" as noted above, pandemic influenza vaccines are the most effective method to prevent and control a pandemic outbreak within a population.

The rights-based discourse is largely focused on the extent to which citizens of states can use the right to health in order to compel the state to act in a certain way to improve individuals' health, such as providing for access to specific medicines. This rights-based approach has been particularly successful in improving access to medicines in developing states, particularly HIV/AIDS medicines.[13] Within the context of access to medicines, the state's attempt to fulfill this positive obligation has typically manifested itself through legislative or policy changes intended to improve access, such as limiting the patentability of pharmaceutical products,[14] the issuing of compulsory licenses,[15] or using nationalized manufacturers to cheaply manufacture medicines.[16] However, very little academic commentary has been generated regarding access to a vaccine as a component of the right to health.

To this end, access to medicines, as a component of the right to health, was elaborated upon in the Committee on Economic, Social and Cultural Rights' General Comment No. 14: the Right to the Highest Attainable Standard of Health.[17] General Comment 14 holds that states have a tripartite obligation to *respect, protect, and fulfill* the right to health.[18] Within the context of access to pandemic influenza vaccines, two of the "core obligations" of states are relevant:

> States must ensure provision of health care, including immunization programmes against the major infectious diseases.[19]
> The creation of conditions which would assure to all medical service and medical attention in the event of sickness...includes the provision of equal and timely access to basic preventive, curative, rehabilitative health services and...the provision of essential drugs.[20]

It is clear that providing full access to vaccines during an influenza pandemic would enable a state to discharge its obligation fully in this regard. However, it remains unclear to what extent states can fail to provide full access to pandemic influenza vaccines (for whatever reason) and still be considered to have discharged their obligation. Indeed, the right to health is progressive – generally, states party to the ICESCR undertake to

> [t]ake steps, individually and through international assistance and co-operation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized in the present Covenant by all appropriate means, including particularly the adoption of legislative measures.[21]

This Article of the Covenant is not particularly helpful when seeking to determine if, and when, a state party can be said to have discharged its right to health obligations. It is weakly worded and filled with uncertainty, particularly in relation to what "the maximum of its available resources," "achieving progressively," and "all appropriate means" relate to.[22] Given that a sufficient benchmark for a state having discharged its obligations in relation to access to vaccines is not provided in the ICESCR, it is necessary to turn to General Comment 14 for further guidance. In the context of access to medicines, the provision of 'essential' medicines is a core, non-derogable obligation, which states must fulfill as a minimum criterion to meet their obligations under the Covenant.[23] The ICESCR does not provide an exhaustive list of which drugs constitute "essential medicines," instead relying upon the WHO Model List of Essential Drugs.[24] While not listed on the current Essential Drugs list,[25] influenza vaccine was listed as an essential medicine on the 2009[26] and 2010 lists[27], when 2009-H1N1 was prevalent. It is likely that during a future influenza pandemic an influenza vaccine will again be listed on the WHO Model List of Essential Drugs, and therefore be considered an essential medicine for the purposes of the right to health.

The Right to Health, and Access to Pandemic Influenza Vaccines

During the most recent influenza pandemic (2009-H1N1), despite the clear obligation to provide pandemic influenza vaccines as an essential medicine, access to the vaccine was very poor in developing states. Most developing states either were not accessing the vaccine at all, or were accessing it significantly later than their developed neighbors.[28] If a rights-based approach to 2009-H1N1 were adopted, one could argue that developing states failed to meet their obligations regarding the right to health by failing to provide an "immunization programme against a major infectious disease"[29] and failing to "provide essential drugs"[30] for their population during 2009-H1N1. However, such an approach may be too simplistic; developing states have long complained that they are unable to access influenza vaccines during a pandemic, despite their best efforts.[31] This serves to highlight one of the significant drawbacks with the rights-based narrative regarding access to medicines in developing states: it presupposes that the state is capable of adequately addressing the problem with the resources that it has available to it. What of the state that lacks the means to secure access to medicines on behalf of its population? It would of course be unfair to claim that such states have failed to meet their positive obligations in regards to the right of health, when they lack the means to discharge the obligation.

This is neatly highlighted by contrasting Article 2(1) of the ICESCR, which states that

> [e]ach State Party to the present Covenant undertakes to take steps, individually and through international assistance and co-operation, especially economic and technical, to the *maximum of its available resources,* with a view to achieving progressively the full realization of the rights recognized in the present Covenant by all appropriate means, including particularly the adoption of legislative measures[32] [emphasis added]

With paragraph 47 of General Comment no. 14, which states that

> [i]f resource constraints render it impossible for a State to comply fully with its Covenant obligations, it has the burden of justifying that every effort has nevertheless been made to use all available resources at its disposal in order to satisfy, as a matter of priority, the obligations outlined above. It should be stressed, however, that a State party cannot, under any circumstances whatsoever, justify its non-compliance with the core obligations set out in paragraph 43 above, which are non-derogable.[33]

Both the provision of essential drugs[34] and the provision of immunization against major infectious diseases[35] are *core* obligations within General Comment 14. Therefore, it is clear that not providing vaccines during an influenza pandemic constitutes a failure on the part of a state to meet its ICESCR obligations regarding the right to health, and resource constraints are not an adequate justification for failing to provide pandemic influenza vaccines. In short, states, including developing ones, must provide pandemic influenza vaccines to their population, or they will not have fulfilled their obligations under the ICESCR.

DISCHARGING THE OBLIGATION

In order to evaluate the extent that the PIP Framework can enable a developing state to discharge its right to health obligations in respect of access to pandemic influenza vaccines, it is necessary to make a determination regarding the threshold of vaccine access that needs to be met by a state in order for it to be considered to have discharged its obligation. On this point, General Comment no. 14 states that "[f]unctioning public health and health-care facilities, goods and services, as well as programmes, have to be available in sufficient quantity within the State party,"[36] but no further guidance is provided as to what "sufficient quantity" means in this context. Within this paper, the notion of "sufficient access" is used, which is based on two interlocking factors: vaccination levels and vaccination timings. If a state achieves sufficient access to vaccines during an influenza pandemic, it is considered to have satisfied the requirements to have discharged its obligations regarding the right to health – full vaccination is not required to have discharged right to health obligations in this context.

Vaccination Levels

When discussing access to oral solid dose drugs, it is fairly straightforward to determine when a state has discharged its right to health obligations in respect of access to that drug – the right can be said to be discharged when all patients that require access to that drug have access. For example, the antiretroviral drug zidovudine, which is used to treat HIV infections, appears on the WHO Essential Medicines list,[37] and therefore access to zidovudine constitutes a core obligation under General Comment no. 14, in much the same

way that access to pandemic influenza vaccines is likely to during a future pandemic. The right to health obligations in respect of zidovudine can be said to have been discharged when there is ready access to zidovudine for all patients who require it in order to treat their HIV infection. However, that is not the case when discussing vaccines – the beneficial effects of a vaccine are not just felt by the individual receiving the vaccine, but by those in the wider community too, due to community immunity.[38]

Due to the mutations that occur with each strain of influenza virus, the vaccination coverage required in order to establish community immunity has fluctuated with each pandemic since 1900.[39] Aside from 2009-H1N1, which was noted for having a having a particularly low mortality and infection rate[40] when compared with more typical pandemics,[41] a minimum vaccination coverage of at least 33% has been required in all pandemics in order to establish community immunity and slow down the rate of infection.[42]

When discussing access to pandemic influenza vaccines as a right to health obligation, we are not just discussing access to pandemic influenza vaccines on an individual basis, but also the right to *benefit* from the herd immunity, which is established within a community when sufficient vaccine is administered. To that end, enough vaccine to immunize at least 33% of a state's population will be taken to be 'sufficient access'. This threshold is taken as it is sufficient to provide the beneficial effects of community immunity. Therefore, if sufficient vaccine has been procured in order for community immunity to be achieved within a population, it is possible to argue that the state's right to health obligations have been discharged in respect of pandemic influenza to the entire community that is benefiting from the immunisation campaign, not just the individuals that have received the vaccine directly.

Vaccinating Timings

Pandemic influenza strains predominantly emerge in, and spread rapidly through, developing states.[43] The states that are at a heightened risk from pandemic influenza are the most likely to be reliant upon donations from the WHO to gain access to pandemic influenza vaccines.[44] These donations from the WHO arrive in much smaller batches than in developed states, and much later than in self-procuring developed states.[45] This significantly hampers these states' abilities to combat pandemic influenza outbreaks, meet community immunity thresholds, and limit or prevent the spread of the disease beyond its borders. Therefore, it is not just the amount of pandemic influenza vaccines that a state can access that is of relevance to this research, but also when access is gained.

As the timing of vaccination administration is important for an effective domestic and international response to the pandemic, for the purpose of this research a state can be said to have discharged its right to health obligations in respect of pandemic influenza vaccines if its population has access to the vaccine within the same timeframe as developed states.

USING THE FRAMEWORK TO DISCHARGE THE OBLIGATION

The PIP Framework envisages that the WHO manage a stockpile of "around 150 million vaccines"; 50 million doses of the stockpile will be for use in "affected countries, according to public health risk and need, to assist in containing the first outbreak or outbreaks of an emerging pandemic" and "100 million for distribution...to developing countries that have no or inadequate access to...influenza vaccines, on a per capita basis that can be distributed to affected and at risk developing states during a pandemic."[46]

Since the creation of the Framework in 2011, the major developments in this area have been focused on the Standard Material Transfer Agreements (SMTAs) that the WHO has negotiated. The success of the Framework hinges upon the uptake of SMTAs by

pandemic influenza vaccine manufacturers, and the terms and conditions to which they are willing to agree. In the most recent review of the pandemic influenza vaccines manufacturing capacity, Partridge & Kieny (on behalf of the WHO) identified twenty-four manufacturers that are active in manufacturing pandemic influenza vaccines.[47] In addition to this categorization of influenza manufacturers, the WHO, when calculating partnership contributions for the running costs of the Global Influenza Surveillance and Response System (GISRS), identifies those influenza vaccine manufacturers using the WHO GISRS, in order for them to contribute to the running costs.[48] Of those manufacturers identified by Partridge & Kieny, eighteen also make partnership contributions to the WHO, on the basis that they use the WHO-GISRS.[49] Use of GISRS is understood to include receipt of physical materials, or use of data and/or information, some of which may not be routinely provided to the general public.[50] Uptake of SMTAs by pandemic influenza vaccine manufacturers was initially slow, and despite the fact that eighteen active pandemic influenza vaccines manufacturers benefited from the work of GISRS, from 2011-late 2016 only three of these manufacturers had an SMTA2 in place, with only 46 million doses being committed to the Stockpile.

However, more recently, there has been a proliferation of Agreements being signed with pandemic influenza vaccine manufactures, and to date the WHO has signed SMTAs with eleven pandemic influenza vaccine manufacturers. All of these manufactures have committed to donating 7.5%-9% of their 'real-time' pandemic influenza manufacturing output to the WHO to supply the stockpile.[51] The exact number of doses within the PIP Stockpile are not known, but the WHO has stated that it is "approximately three times the amount of pandemic vaccine available [to the WHO for distribution] during the H1N1 pandemic." Given that the stockpile the WHO managed during 2009-H1N1 distributed 78 million doses,[52] it is reasonable to assume that the stockpile currently holds around 230 million doses. Such a drastic increase in the capacity of the Stockpile is clearly welcome, but it is necessary to determine to what extent this increase in commitments to the PIP Stockpile is likely to improve the extent to which developing states can use Framework to discharge their right to health obligations in respect of access to pandemic influenza vaccines.

In respect of the "vaccination timing" element of the criterion against which we are judging the utility of the PIP Framework, it is it is clear that the one major benefit of the PIP stockpile is the removal of the time delay of donated vaccine being committed to the WHO, which has been a barrier to discharging the obligation during previous influenza pandemics.[53] However, this benefit may not actually be realized in practice during the next pandemic. During 2009-H1N1, governments of developed states with domestic manufacturing capacity restricted exports to other territories, and to the WHO, until domestic demand had been fulfilled,[54] and concern has been expressed by pandemic influenza vaccine manufactures that member states with domestic pandemic influenza vaccines production within their territory will place restrictions upon exports of vaccines that have been committed to the PIP stockpile, until domestic demand had been fulfilled.[55] Indeed, the Framework makes provision for such an event occurring, holding "no Party shall be liable for any delay in the performance of or failure to perform its obligations under this Agreement, where such a delay or failure is caused by Force Majeure,"[56] including "embargo or requisition" and "acts of government."[57] Member States with domestic pandemic influenza vaccine manufacturing capacity have given assurances to the WHO that they would enable domestic manufacturers to fulfill their SMTA2 commitments without government interference;[58] however, despite this, government requisition is a very real possibility, particularly during a severe pandemic. Such a requisition causing a delay to the real-time commitments to the Stockpile, and onward transfer to developing states would severely impact on the ability of a developing state to use the PIP stockpile in order to discharge its right to health obligation in respect of pandemic influenza vaccines.

The utility of the Stockpile to enable developing states to discharge their right to health obligation in respect of pandemic influenza vaccines appears less viable when vaccination levels are taken into consideration. The idea that the PIP Stockpile would be insufficient to rectify inequities in access to vaccines during a pandemic was addressed before the Stockpile went live, with scholars noting that even if the PIP Stockpile secured the 100 million doses to distribute to "developing states in need" as initially anticipated, this would provide for a vaccination level of approximately 1.8% of the population of developing states, even if a single dose regime was viable.[59] However, since this time, the capacity of the Stockpile has grown considerably, beyond that which was initially envisaged by the WHO. The current PIP stockpile has approximately 230 million doses committed to it. However, not all of this stockpile is reserved specifically for developing states that are unable to procure Pandemic influenza vaccines on the open market.

If the WHO maintains the proportions at which it intended to distribute the donated vaccine with

> One-third 'for use in affected countries, according to public health risk and need, to assist in containing the first outbreak or outbreaks of an emerging pandemic', two-thirds to 'developing countries that have no or inadequate access to H5N1 influenza vaccines, on a per capita basis, with use to be determined by those countries.[60]

Assuming that two-thirds of this Stockpile is reserved for "developing states in need," the stockpile could ensure a vaccination level coverage of 4.14% in developing states on a one-dose strategy, and 2.07% on a two-dose strategy, which is much more typical of an immunization campaign against pandemic influenza. Both of these vaccination coverage levels are significantly below the target of 33% needed to establish herd immunity within a population. While the PIP Stockpile was not explicitly created with the 33% vaccination target in mind (nowhere in the drafting or the final text was a vaccination coverage target set), the herd immunity level of 33% is well established within the literature as the most desirable vaccination coverage target. In relation to this target, clearly, the commitments provided in the example SMTA2 do not make procurement from the PIP stockpile a particularly attractive procurement option for developing states, particularly if a developing state is seeking to procure sufficient vaccine in order to establish herd immunity levels within their territory in order to discharge their right to health obligations.

The low uptake of SMTAs amongst pandemic influenza vaccines manufacturers, combined with the reduced commitments being given by pandemic influenza vaccines manufacturers in those SMTAs that have been concluded, make the PIP stockpile an undesirable procurement method for developing states. Moreover, even when all of the vaccine that has been committed to the WHO via SMTAs has been delivered, it is likely that the WHO will need to seek donations from pandemic influenza vaccines manufacturers (outside of SMTA2 commitments) and developed states in order to be able to meet the procurement needs of developing states, in much the same way they did during 2009-H1N1. This is a particularly undesirable scenario because, when making appeals for donated vaccine, the WHO will again have "little leverage to influence developed countries [and Pandemic influenza vaccines manufacturers] other than rhetoric about equity, justice, and solidarity."[61] If the WHO must again make appeals to equity and justice in order to procure vaccine to donate to developing states, as appears likely, it will highlight the significant shortcomings in the PIP Framework, which was designed specifically to minimize such a scenario during a pandemic.

RECOMMENDATIONS

Moving forward it would be beneficial if the WHO placed greater emphasis on transfer of technology in the SMTA negotiations. The PIP Framework envisages that manufacturers concluding an SMTA with the WHO may have agreed to transfer technical knowhow regarding the manufacturing of pandemic influenza vaccines to the WHO, for onward transfer to developing states. However, none of the eleven manufactures that have SMTAs with the WHO has agreed to transfer technology as part of their Agreements. The onward transfer of technology from established pandemic influenza vaccine manufacturers to developing states could allow these developing states to establish pandemic influenza vaccine manufacturing capacity, which they could procure from when needed. If developing states were able to manufacture sufficient levels of pandemic influenza vaccines in order to achieve herd immunity, they could discharge their right to health obligations without being reliant upon procurement from established pandemic influenza vaccine manufacturers in developed states or receiving donations from the WHO, both of which are unviable procurement options for developing states. The importance of transfer of technology to the success of this model has been noted by the World Health Assembly and the Developing Countries' Vaccine Manufacturing Network.[62]

Indeed, transfer of technology from an established vaccine manufacturer to Brazil has led to the state pharmaceutical manufacturer in Brazil, the Butantan Institute, to establish manufacturing capacity in the field of pandemic influenza vaccines. In 2011, the Butantan Institute delivered the first batch of vaccines against influenza entirely produced in Brazil. Currently, the Butantan Institute is able to manufacture both seasonal and pandemic influenza vaccines[63]and has manufacturing capacity for approximately 20 million doses.[64] While it is important to note that this is not sufficient manufacturing capacity to meet the target to immunize 33% of the Brazilian population,[65] and thereby discharge the right to health obligations, it is sufficient for approximately 10% coverage. This figure is significantly higher than the 4.4% vaccination coverage that is the best case scenario that could be achieved by developing states procuring from the PIP Framework.

CONCLUSION

This paper has argued that that direct procurement from the PIP Stockpile is not a viable option for developing states seeking to obtain sufficient access to pandemic influenza vaccines in order to discharge their right to health obligations. In the context of the right to health, the PIP Framework does provide one distinct benefit: if developing states were to procure vaccines from the PIP Stockpile, then these vaccine would be distributed within the same timeframe as developed states.[66] While this is a clear benefit over procurement during 2009-H1N1, procurement from the PIP Stockpile merely satisfies one element of the two-part test outlined earlier in this paper. The second element of the two-part test, procuring sufficient levels of vaccine to immunize at least 33% of their population, cannot be satisfied by procurement via the PIP Framework. Therefore, a developing state cannot fulfill and discharge its right to health obligations in respect of pandemic influenza vaccines by relying upon procurement from the PIP Framework. With this is mind, it is reasonable to argue that the PIP Framework is not able to ensure that developing states are able make use of the Stockpile in order to discharge their core right to health obligations in respect of pandemic influenza vaccines, as mandated by General Comment 14.

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[9] Standard Material Transfer Agreements is the method by which the WHO enters into agreements with entities outside the WHO GISRS, such as pharmaceutical companies that manufacture pandemic influenza related products such as vaccines or antivirals. SMTA2's have provisions related to benefit sharing included within them.

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[18] Ibid, Para. 33.
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